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Dockets Management Branch (HFA-305)
Docket No. 98-N-1265
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, MD 20857

Greetings:

I write to OPPOSE the FDA-proposed draft MEMORANDUM OF UNDERSTANDING, DOCKET No.98N-1265. The definition of "inordinate amount" is of special concern because it could easily restrict availability for me of essential individually-compounded medications I receive from an out-of-state compounding pharmacy and thus directly affect my health.

FROM A MEDICAL STANDPOINT: For persons with difficult or rare medical problems, there is *often* no in-state access to certain medications, as is the case in my state (Washington) where population and demand is not great enough to support any compounding pharmacies. Cutting current access would unnecessarily and certainly sentence many people, including myself, to sickness rather than cure. (Besides the obvious desirability of health, illness is more expensive for the individual, insurance companies, and government.)

FROM A LEGAL STANDPOINT: Further, the way this is handled seems like restraint of trade. At a time when some insurance companies even prefer that standing medications be ordered through a central national pharmacy source with which they've contracted and when the Internet makes every local drugstore a possible national one and creates sites intended for national prescription ordering, this restriction seems inconsistent.

FROM AN POLICY STANDPOINT: The phrase "inordinate amounts" in the docket is completely open for interpretation and potentially unfair use. As a guideline it is worthless; does it mean 100 prescriptions or 1,000

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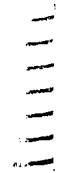
or 10,000 per week, per month, per year... what? Does it mean different amounts in different states? This phrase alone could mean that my medication could arbitrarily be cut off by an FDA or state board official who – on an invisible basis that neither the pharmacy nor or the patient in need might know or be able to determine – simply decides that “inordinate” has been reached. The the proposal only intimidates pharmacies currently helping patients – patients who have already had difficulty finding the medications and supplements they need. Importantly, the proposal interferes with doctors and patients abilities to work out administration of totally legal medications. If the FDA has any interest in the day-to-day availability of medications, it should be interested in more availability rather than less.

This policy is not in the best interest of the FDA, patients or the general public and at best it's unclear as to who would truly and fairly benefit from this restriction.

I ask that you drop this proposal.

Sincerely,





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